



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

August 20, 2015

Kinetic Concepts Incorporated USA
Ms. Margaret Marsh
Technical Director, Regulatory Affairs
6203 Farinon Drive
San Antonio, Texas 78249

Re: K141017

Trade/Device Name: Prevena Incision Management with Peel & Place Dressing
Prevena Incision Management with Customizable Dressing Systems
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: Class II
Product Code: OMP
Dated: August 3, 2015
Received: August 5, 2015

Dear Ms. Marsh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number (if known)

K141017

Device Name

Prevena Incision Management System with Peel and Place Dressing
Prevena incision Management System with Customizable Dressing

Indications for Use (Describe)

The Prevena Incision Management System is intended to manage the environment of surgical incisions that continue to drain following sutured or stapled closure by maintaining a closed environment and removing exudate via the application of negative pressure wound therapy.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY
Prevena Incision Management with
Peel & Place Dressing and Customizable Dressing

Submitter Information [21 CFR 807.92(a)(1)]			
Name	KCI USA, Inc. (Kinetic Concepts, Inc.)		
Address	6203 Farinon Drive San Antonio, TX 78249		
Phone number	210-255-6481		
Fax number	210-255-6727		
Establishment Registration Number	3005178245		
Name of contact person	Margaret Marsh, Technical Director, Regulatory Affairs		
Date prepared	August 18, 2015		
Name of the device [21 CFR 807.92(a)(2)]			
Trade or proprietary name	Prevena Incision Management with Peel & Place Dressing and Customizable Dressing Systems SKUs: PRE 1055US; PRE 2055US; PRE1001US; PRE2001US		
Common or usual name	Negative Pressure Wound Therapy System		
Classification name	Negative Pressure Wound Therapy Powered Suction Pump (and components)		
Classification panel	General and Plastic Surgery		
Regulation	878.4780		
Regulatory Class	II		
Product Code(s)	OMP		
Legally marketed device(s) to which equivalence is claimed [21 CFR 807.92(a)(3)]	Prevena Incision Management System with Peel & Place Dressing (K100821) Prevena Incision Management System with Customizable Dressing (K123878) V.A.C.Ultia Negative Pressure Wound Therapy System (K100657)		
Device description [21 CFR 807.92(a)(4)]	<p>The Prevena Incision Management System provides surgical incision management via the application of negative pressure wound therapy over an incision site that has been surgically closed with sutures or staples. The Prevena System is applied to the incision site immediately after surgery for a minimum of 2 days up to a maximum of 7 days depending on the surgeon's preference.</p> <p>The Prevena Incision Management System consists of:</p> <ul style="list-style-type: none"> • A Prevena Dressing (Prevena Peel & Place Dressing or Prevena Customizable Dressing and • A source of negative pressure wound therapy, which may be one of the following KCI therapy units with its associated canisters: <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%; text-align: center;"> <ul style="list-style-type: none"> ○ Prevena 125 Therapy Unit ○ V.A.C. Freedom Therapy Unit ○ V.A.C. ATS Therapy Unit </td> <td style="width: 50%; text-align: center;"> <ul style="list-style-type: none"> ○ ActiV.A.C. Therapy Unit ○ InfoV.A.C. Therapy Unit ○ V.A.C.Ultia Therapy Unit </td> </tr> </table>	<ul style="list-style-type: none"> ○ Prevena 125 Therapy Unit ○ V.A.C. Freedom Therapy Unit ○ V.A.C. ATS Therapy Unit 	<ul style="list-style-type: none"> ○ ActiV.A.C. Therapy Unit ○ InfoV.A.C. Therapy Unit ○ V.A.C.Ultia Therapy Unit
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Indications for use [21 CFR 807.92(a)(5)]	The Prevena Incision Management System is intended to manage the environment of surgical incisions that continue to drain following sutured or stapled closure by maintaining a closed environment and removing exudate via the application of negative pressure wound therapy.
Summary of the technological characteristics of the device compared to the predicate device [21 CFR 807.92(a)(6)]	
Negative Pressure Wound Therapy is the technological principal for both the subject and predicate devices. Application of negative pressure to an incision site that is closed via staples or sutures helps draw the incision edges together and removes fluid from the incision site. The occlusive drape of the dressing provides a negative pressure environment and protects the incision from external contamination.	
At a high level, the subject device and predicate device are based on the following same technological elements:	
<ul style="list-style-type: none"> The dressings that are applied over the incision site in the operating room are identical. One of the following dressings may be selected by the surgeon, based on incision length and geometry: <ul style="list-style-type: none"> The Prevena Peel & Place Dressing (cleared under K100821) which can be used for linear incisions up to 8 inches, or The Prevena Customizable Dressing (cleared under K121883), which can be configured for non-linear incisions or linear incisions longer than 8 inches A negative pressure pump (therapy unit) is required that can provide -125 mmHg of negative pressure continuously to the dressing for a maximum of 7 days. The dressings are connected to the therapy unit via a disposable canister. Incision fluid is collected into the disposable canister The therapy unit provides alarms that indicate when negative pressure wound therapy may be compromised (e.g., visual and audible alarms indicating blockage in the tubing line, an air leak in the system, when the canister is full or batteries are low). 	
The following technological differences exist between the subject and predicate devices:	
<ul style="list-style-type: none"> The V.A.C.Ultia Therapy System offers the option of instillation of topical wound treatment solutions and suspensions over the wound bed (V.A.C. VeraFlo Therapy). However, the Prevena Peel & Place and Prevena Customizable Dressings cannot and should not be used with VeraFlo Therapy, as instillation is not indicated for use over closed incisions. V.A.C.Ultia Therapy system is not intended for home use, and cannot transition home with the patient. 	
Performance Data [21 CFR 807.92(b)]	
Summary of non-clinical tests conducted for determination of substantial equivalence [21 CFR 807.92(b)(1)]	
The following performance data were provided in support of the substantial equivalence determination.	
Prevena Dressing Pressure Manifold Test with V.A.C.Ultia Therapy Unit:	
The average distribution of negative pressure across the full length of the Prevena Dressing on a simulated wound bed under both wet and dry conditions demonstrated that the V.A.C.Ultia Therapy Unit provides an acceptable source of negative pressure at -125 mmHg.	

Summary of clinical tests conducted for determination of substantial equivalence or of clinical information [21 CFR 807.92(b)(2)]

No clinical tests were necessary. However:

- Usability testing of the *Prevena Clinician Guide* and the *V.A.C. Ulta Instructions for Use* was conducted with both 15 surgeon and 15 OR surgical nurse participants. The testing assessed labeling revised to add instructions for using the V.A.C.Ulta Therapy Unit with the Prevena Dressings. In summary, participants were asked to select the appropriate components from a storage area, apply the Prevena Dressing to a simulated incision model in the OR, connect the dressing to a V.A.C.Ulta Therapy Unit and then select the appropriate therapy settings and confirm patient discharge restrictions. Subjects had the opportunity to use product labeling in completing usability tasks. All of the new and critical tasks relating to usability of the V.A.C.Ulta Therapy Unit with the Prevena Dressings were safely completed. Usability test results did not require changes to the user interface or product labeling.
- Usability testing was also conducted with 15 patient user participants on a revised *Prevena Patient Guide*. The testing assessed the ability of the patient user to read the revised *Prevena Patient Guide*, to understand that the V.A.C.Ulta Therapy Unit should not be in the home and to know what to do should this occur. The testing confirmed that patients were able to recognize the V.A.C.Ulta Therapy Unit should not be in their home and to call their clinician for the appropriate therapy unit for use at home. Usability test results did not require changes to the user interface or product labeling.

Conclusions drawn [21 CFR 807.92(b)(3)]

The Prevena Incision Management System and its predicate (K100821 and K123878) are substantially equivalent in terms of safety, function and indications for use.